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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,238	09/12/2003	Rene Verdonk	920522-94798	6848

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EXAMINER

ALI, SHUMAYA B

ART UNIT	PAPER NUMBER
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3771

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.		Applicant(s)	
	10/661,238		VERDONK ET AL.	
	Examiner		Art Unit	
	Shumaya B. Ali		3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-12 and 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 1-18 are pending in the current application. Claims 7 and 13 were previously withdrawn.

Response to Amendment

Drawings filed on 10/30/06 and 11/07/0 are not in compliance with 37 CFR 1.121(d)(1), therefore drawings are not considered. In addition to Replacement Sheets containing the corrected drawing figure(s), applicant is required to submit a marked-up copy of each Replacement Sheet including annotations indicating the changes made to the previous version. The marked-up copy must be clearly labeled as "Annotated Sheets" and must be presented in the amendment or remarks section that explains the change(s) to the drawings. See 37 CFR 1.121(d)(1). Failure to timely submit the proposed drawing and marked-up copy will result in the abandonment of the application.

Amendment to specification, filed on 11/7/06 has been acknowledged.

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Response to Arguments

In regards to the telephone interview granted on 10/25/2006, Examiner discussed claim rejections under 35 USC 101 issues raised in the previous office action. Applicant was suggested to overcome the 101 rejections by incorporating "adapted to" language, however informed that such changes would not invoke claim in condition for allowance. Applicant was further informed that an updated search would be performed prior to establishing decisions on

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patentability. No agreement as to patentability was reached, therefore, Applicant's argument filed on 10/25/06, on page 10 lines 1-11 of the remarks with respect to patentability solely based on issues presented during the phone interview is not well taken.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. However, Applicant is requested to resubmit the foreign priority document because priority document does not seem to show visible ribbon/seal.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4,5,8,12,14, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 4, line 2; claim 8, lines 1 and 2; and claim 14, line 2, the word "means" is preceded by the word(s) "positioning" and "fastening" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Regarding claims 5 and 18, line 2, the terms "settable continuous passive motion" and "an automated way" are considered indefinite. Claimed terminologies, a settable continuous

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passive motion and an automated way are vague because metes and bounds of those terminologies cannot be determined.

Claim 12 recites the limitation "the first" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3,4,6,8,11,15,17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Kelly et al. US 5,529,573.

As to claim 1, Kelly in figure 1 discloses a portable device for providing continuous passive motion, the portable device comprising a brace (10) and a drive mechanism (38), wherein the portable device is adapted for providing continuous passive motion of a limb of a human or animal body having a torso, the limb comprising a distal end and a proximal end, the distal end being connected to the proximal end with a first joint, the proximal end being connected to the torso with a second joint (see fig.1A), wherein said brace is adapted for supporting the distal end of the limb (see fig.1A); wherein said drive mechanism is adapted for providing a settable continuous passive motion of the first joint and/or the second joint of the limb (col.2 lines 36-61), said drive mechanism being coupled to said brace and controlling movement of the distal end of the limb (at control points 16 and 17); said passive motion is

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controlled in a first control point (16) and a second control point (17) on the distal end of the limb; and said drive mechanism comprises at least a first unit (36) for controlling movement of said first control point on distal end of the limb (col.4 lines 24-40).

As to claim 3, Kelly discloses wherein the device furthermore comprising means for immobilizing said second control point of the distal end of the limb (immobilizing control point using 34, see also “fixed in position” in col.3 lines 41-43).

As to claim 4, Kelly discloses a portable device according to claim 1 wherein said portable device furthermore comprises flexible positioning means (24) provided with a fastening means (25,28) positioning said brace and said drive mechanism on the body of a patient carrying said device in a stable position, whereby said drive mechanism is at least partially housed within said positioning means (see fig.1A).

As to claim 6, Kelly discloses wherein the brace comprises a support for said distal end (14) of the limb comprising a first primary sub-frame for supporting said distal end of the limb, a support for said proximal end of said limb comprising a second primary sub-frame (17) supporting said proximal end of the limb, a hinge (23) for connecting said support for said distal end of the limb to said support for said proximal end of the limb.

As to claim 8, Kelly discloses wherein said positioning means comprises an inflatable housing (19) of flexible material provided with a fastening means (16,42), said housing allowing at least partial deformation when fastened on a body for providing a stable position (col.6 lines 27-50).

As to **claim 11**, Kelly discloses wherein said brace for supporting the distal end of the limb is adjustable in order to fit the length of the distal end of the limb of the user (col.4 lines 24-40).

As to **claim 15**, Kelly discloses wherein the device further comprising a remote control unit (34) for controlling the passive movements provided by the device.

As to **claim 17**, Kelly discloses wherein the device further comprising two connectors, provided a the upper side of the device, whereby one connector (wire connecting 34 to 30) is connected to the remote control unit and the other connector is connected to an electric transformer (36) or one or more batteries.

As to **claim 18**, Kelly discloses wherein the passive limb movements provided by the device are provided in an automated way (via electronic control means, 34)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2,5,12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly et al. US 5,529,573.

As to claim 2, Kelly lacks wherein said drive mechanism further comprises a second unit for controlling the movement of said second control point of the distal end of the limb. However, Kelly teaches one drive unit for both first and second control point (col.3 lines 25-59). Since one control unit is capable of providing the same function as the second unit as claimed, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a second control unit, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St Regis Paper Co. V. Bemis Co.*, 193 USPQ 8.

As to claim 5, Kelly lacks wherein said drive mechanism for providing a settable continuous passive motion of said limb is a programmable motor. However, Applicant has not established why “programmable” motor is crucial in terms of providing a specific function or

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unexpected outcome over prior art. Therefore, it is an obvious matter of design choice because using either a programmable or non-programmable motor would not have affected ability of the device to provide CPM. Therefore, it would have been an obvious matter of design choice to modify Kelly to obtain the invention as specified in claim 5.

As to claim 12, Kelly lacks wherein the first and second motor unit consists of a triple spindle with electromotor with worm wheel transfer, being provided in a housing, allowing the motor units to induce a substantially vertical moment. However, no criticalities has been established in the disclosure in terms of claimed motor provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with control unit 36 disclosed by Kelly because the ability of the device to provide CPM is not affected by the type of motor used. Therefore, it would have been an obvious matter of design choice to modify Kelly to obtain the invention as specified in claim 12.

As to claim 14, Kelly lacks wherein the positioning means further comprises belts provided with fasteners for positioning said device on a body. However, Kelly teaches fasteners (28,24,23) which are considered equivalent in the art for providing the positioning function as claimed. Therefore, the selection of any of the known equivalents fastener would be within the level of ordinary skill in the art.

Claims 9,10, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelly et al. US 5,529,573 in view of Saringer et al. US 5,738,636.

As to claim 9, Kelly lacks wherein said support of the distal end of the limb of said brace is furthermore provided with a limb fastener, and said support of the proximal end of the limb of

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said brace is furthermore provided with a limb fastener. **As to claim 10**, Kelly further lacks wherein said fasteners for the distal end and the proximal end of the limb comprise fixing straps. However, Sartinger teaches claimed strap and father teaches hook and loop type straps are considered "fixing straps" since they are capable of fixing the device to a wearer in a secure position. Sartinger's straps allow securing of a brace to the user's body (see col.4 lines 22-28). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide limb fastener and fixing straps to the device of Kelly for the purpose of securing the device to the user's limb as taught by Sartinger.

As to claim 16, Kelley discloses wherein said remote control unit comprises control switches (32), however lacks a visual display screen, however, Saringer's figure 12 discloses a brace with a controller, more specifically a front panel which is considered "a visual display screen" for indicating whether the user has started (as indicated by a hand symbol in fig.12) or stopped (as indicated by another symbol next to a stop label) a program for controlling a joint movement. The user depresses switch (204) to provide ankle (joint) movement and when the switch is released to stop actuator or to program the range of motion (see col7 lines 55-64). Therefore, it would have been obvious to one of ordinary skills in the art at the time the invention was made to provide a visual display screen to the device of Kelley for allowing the user to have a visual representation of the type of program that is being set or adjusted to limit the range of motion for a joint movement as taught by Saringer.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Backman (5,236,411), Funk (4,651,719), Pecheux (4,905,677), Luttrell (5,117,814),

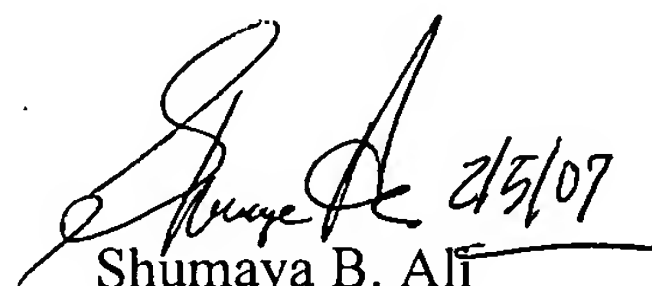
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Burkhead (5,385,536), Bastyr (5,407,420), Kaiser (5,891,061), Sainger (5,951,499), and Sato (6,146,341) are cited to teach body motion controlling device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Shumaya B. Ali
Examiner
Art Unit 3771


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2/5/07